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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,852	10/05/2005	Vitus Maria Huber	NOS-106	9598

EXAMINER
MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
10/30/2007	PAPER

7590 10/30/2007
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,852	Applicant(s) HUBER ET AL.	
	Examiner Kristen C. Matter	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,15,17,20-31,34-46 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,15,17,20-31,34-46 and 48-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the amendment filed on 9/18/2007. Claims 1, 21, 22, 25-27, 36, 39, 42, and 48 have been amended, claim 5 has been cancelled, claim 13 has been withdrawn from consideration, and claim 52 has been added. Currently, claims 1, 3, 4, 15, 17, 20-31, 34-46, and 48-52 are pending in the instant application.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tension element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilms (US 1, 213, 786).

Regarding claims 1, 3, 4, 15, 20, and 23, Wilms discloses a foot treatment device comprising a first fastening portion in the region of the big toe (20), a second fastening portion in a region of the central foot (27), and a hinged flexible splint extending along the inner foot for correction toe joint articulation (11, 25, 16). The device consists of two hinged splint shanks (11, 25) with a lenticular cross-section adapted to the shape of a human foot that pivot about an articulated hinge (16) with an axis corresponding approximately to the joint axis of the main big toe (Figure 1). The rivet is considered the hinge mechanism insomuch as it is what allows the rotation of the two hinged splint shanks relative to one another about an axis located where the rivet connects the two shanks. The axis corresponds approximately to the main big toe joint in the direction of flexion and extension as seen in Figure 1 insomuch as the pivot is located on the inside of the foot and is within a short distance of the big toe joint (i.e., the closest human body joint is that of the big toe as opposed to the ankle joint for example).

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Regarding claim 17, Wilms further discloses a foot-spreading pad (32) on the area of the sole of the foot behind the main joints of the toes (Figure 1).

Regarding claim 21, both hinged splint shanks have a free end and an end at the hinge (Figure 1).

Regarding claim 24, the hinge ends of the hinged splint shanks rotate with a rotational symmetry about a pivot axis corresponding approximately to that of the big toe.

Regarding claim 26, a force can be exerted on the big toe in the direction on the inner side of the foot for lateral correction (page 2, lines 15-30).

Regarding claims 29 and 31, the shanks have a three-dimensional form substantially that of a plate with first and second longitudinal boundaries and a narrow boundary (Figure 1) adapted to the anatomical features of a human foot.

Regarding claim 30, Wilms discloses one or more slots (28) in the region of the longitudinal boundary with edges parallel to the longitudinal boundary that form a central stay, and edge stay, and intermediate stays (Figure 1).

Regarding claim 37, the surfaces of the shanks that lie along the users foot are smooth (Figures 3 and 4).

Regarding claim 49, the annular bindings around the central foot and toe are positioned without creating steps (Figure 3).

Regarding claim 51, the device is not fixed rigidly to the foot and allows at least some movement for adapting the position of the hinge axis of the hinge mechanism to the anatomical features of the users foot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms.

Regarding claim 48, Wilms discloses spring metal for forming the shanks, but lacks a plastic shank. However, the feature of choosing a plastic shank instead of a metal shank is considered an obvious design choice since it appears that Wilms flexible metal shank would perform equally well with the plastic shank for allowing the slight bending on the hinge shanks for correction the toe alignment. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claim 50, Wilms is silent as to when the annular bindings are threaded to the second hinge shank. However, claim 50 adds no further structural limitation to the claims and it appears to be a matter of personal preference as to the binding (27) being threaded to the second hinged splint shank prior to application to the patient's foot, so long as the patient is able to slide the foot into the formed loop from the strap and shank.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms as applied to claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Willner et al. (US 5,897,515). Wilms is silent as to the shanks being manufactured from a

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carbon-fibre reinforced plate. However, Willner et al. discloses a foot brace made of a carbon fiber reinforced material as a suitable replacement for prior art metal braces (abstract and column 1, lines 20-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a carbon-fibre reinforced material instead of metal as taught by Willner et al. in the device of Wilms in order to reduce the weight of the brace while maintaining its strength.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms as applied to claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Scholl (US 1,055,810). Wilms is silent as to a tension element for exerting a force on one or more neighboring toes. Scholl discloses a similar toe straightening device with a tensioning element for exerting a force on a neighboring toe (column 2, lines 60-65 and 85-95). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wilms device with a tensioning element as taught by Scholl for applying a force to a neighboring toe in order to straighten the second-toe, which is often distorted by the misalignment of the big toe as well.

Claims 22, 34-36, and 38-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms as applied to claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Tyrrell (US 6,254,559).

Regarding claims 34, 35, 40, 41, 42, 45, and 46, Wilms does not disclose an annular hinge, but rather a rivet hinge with a flexible material that produces the same force on the toe.

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Tyrell discloses an annular hinge with a hinge disk (19, 18) and a hinge ring (12) joined as one piece with a hinge splint shank for use on a hip joint that fixes a flexion extension plane by angles (20, 25) with the pivot axis for correct alignment of the joint members. Cap plate (15) is fixed to the splint shanks by screws (16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the rivet hinge of Wilms with an annular hinge as taught by Tyrell for providing more controlled angular correction of the big toe joint.

Regarding claim 22, the ends near the hinge joint have a three-dimensional form for allowing rotation (i.e., as the person walks, sits, etc.) and for allowing rotation about the pivot axis (i.e., for setting the flexion extension angle). The ends are formed such that the hinge ends can be inserted into each other and interlock (Figure 5). Particularly, once the shaft (23) is connected to the first hinge splint shank, the "multiple" pieces can be considered part of the end of the shank, thereby allowing insertion into the hole on the second hinge splint shank for interlocking.

Regarding claim 36, the modified device of Wilms and Tyrell is silent as to the material thickness of the hinged splint shanks. Absent a critical teaching and/or showing of unexpected results derived from providing a material thickness that tapers towards the edge regions of the shanks, the examiner contends that the material thickness is an obvious design choice that does not patentably distinguish applicant's invention. Furthermore, it appears as though the modified device would perform equally well with the tapered material thickness claimed by the Applicant.

Regarding claim 38, Tyrell discloses an annular ridge (Figure 2 - i.e., indents in 18, 19 or 17). Tyrell is silent as to the ridge being moulded onto the hinge disk. However, "Even though

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product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)(citations omitted).

Regarding claim 39, the axial positioning on the hinge ring relative to the hinge disk operates together with an annular step (17).

Regarding claims 43 and 44, Tyrell discloses that the angle is approximately 20 degrees to the vertical (column 3, lines 10-15), which would produce an angle between 75-115 degrees and 70-110 degrees for α and β depending on how the angles were defined.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilms as applied to claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Dondero (US 7,200,875). To the extent that Wilms is silent as to the hinge ends of the shanks comprising a first shape that is inserted into and interlocked with a second shape of the other hinge shank, Dondero is cited to show that is well known to replace rivets with integrally formed bosses and holes for fastening two separate elements and producing a rotational movement (column 14, lines 13-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the rivet of Wilms with an integrally formed fastener as taught by Dondero for reducing the number of parts of the device.

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Furthermore, it appears as though the device disclosed by Wilms would perform equally well with the integral fastener as opposed to the rivet.

Response to Arguments

Applicant's arguments filed 9/18/2007 have been fully considered but they are not persuasive.

In response to applicant's argument that the Wilms reference does not teach a pivot axis corresponding approximately to the joint axis of the main big toe in the direction of flexion and extension, examiner contends that although the axis is shown in Figure slightly offset from the axis of the main big toe, it is still in a location that can be said to correspond approximately to the axis of the main big toe because it is only a small distance away from the joint and the main big toe joint is clearly the closest joint to which the pivot axis of Wilms lies. There appears to be no other joint that the pivot axis of Wilms could be said to lie approximately to.

In response to applicant's argument that the Scholl reference does not teach a hinge mechanism corresponding to the big toe joint, examiner points out that the Scholl reference is cited merely to show that additional tensioning elements for correcting the position of more than one tow at a time using similar orthoses are well known in the art.

In response to applicant's argument that one of ordinary skill in the art would not look to Tyrell as a replacement for the joint located on the toe, examiner contends it is well known in the art that articulated joints for orthoses can be modified to accommodate various body joints (i.e., elbows, knees, hips, toes, ankles) and therefore, one of ordinary skill in the art could have appreciated the replacement of the rivet of Wilms with a more complex hinge for allowing more

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precise rotation of the two shank members (see Clemens et al. cited below for extrinsic evidence). Whether the device would then fit in a shoe is not commensurate with the scope of the claims and would depend on the shoe being worn and how small the device was modified to be.

In response to applicant's argument that the hinge ends of Tyrell are separated by multiple elements, examiner argues that once the shaft (23) is connected to the first hinge splint shank, the "multiple" pieces can be considered part of the end of the shank, thereby allowing insertion into the hole on the second hinge splint shank for interlocking.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clemens et al. is cited to show articulated joints for use in both hip and toe joints.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270.

The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen C. Matter
Examiner
Art Unit 3771



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10/29/07